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PHONE (202) 225-2927

U.S. House of Representatives

Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce
Washington, DC 20515-6116

May 27, 1994

The Honorable David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

The Food and Drug Administration recently published a proposed rule on the Prescription Drug Marketing Act of 1987 and the amendments to this statute enacted in 1992 (59 Fed. Reg. 11842, March 14, 1994). That proposed rule covers certain requirements regarding the definition of wholesale drug distributors and health care entities.

There are some instances where community blood centers function as full-service blood centers, providing therapeutic apheresis, therapeutic phlebotomies, and diagnostic blood tests for HIV and Hepatitis, as well as providing care for hemophilia. Where these full-service community blood centers are distributors of blood products, they have presumably complied with FDA regulations by registering with their respective states as wholesalers.

Nevertheless, in the FDA's recent Federal Register notice, proposed section 203.3(n) states that:

> " a person cannot simultaneously be a 'health care entity' and a retail pharmacy or wholesale distributor."

This suggests that full-service blood centers that provide legitimate health care, and that have registered with their respective state as a wholesaler, would be prohibited from either providing blood components or plasma derivatives as part of their service, or providing health care or diagnostic service. This could create obvious difficulties for the community blood centers in this position.

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The Subcommittee understands that the Agency included this prohibition not to prevent community blood centers from operating as both a health care entity as well as a wholesaler, but rather to address practices by certain physicians who were abusing the existing system. Specifically, both the Department of Justice and the FDA had determined that there were practitioners operating as health care entities that were purchasing drugs at a discount and reselling them, rather than using them to treat patients.

The Subcommittee understands that the FDA intends to address this issue in order to avoid disrupting the supply of biologics sold as prescription drugs to individuals such as hemophiliacs and individuals with compromised autoimmune systems. The Subcommittee will work with you to resolve this issue so that important services are not disrupted.

Sincerely,

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

cc: The Honorable Dan Schaefer